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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,905	04/02/2001	Sharat Singh	0225-0033.22	2421

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ACLARA BIOSCIENCES, INC.
1288 PEAR AVENUE
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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

23

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/824,905

Applicant(s)
09/824,905

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 21, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The applicant's Response filed 2/21/2003 has been entered-in-part. The part of the amendment showing the sequence listing has not been entered. It should start on a separate piece of paper and should be identical to the CRF provided.

Following the entry of the applicant's amendment, claims 11-24 are pending.

Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

NEW GROUNDS REJECTIONS AS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 11-18 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (5,470,705, issued 1995) in view of Babon et al. (5,851,770, issued 1998).

Since the limitations of claims 19-23 are similar with the limitations of claims 11-18, the teachings of Grossman et al. and Babon et al. are also applied to the limitations of claims 19-23.

Grossman et al. disclose a method of detecting a plurality of different sequences in a target sequence involving a plurality of sequence probe (See column 2, lines 54-56). The probe comprises the features of the e-tag probe. The probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The polymer chain can be polyethylene oxide (PEO) or a polypeptide chain where the chains attached to different-sequence binding polymers (See column 3, lines 11-18). The teachings suggest that the charge/translational frictional drag is consisted of carbon,

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hydrogen, oxygen, phosphorus, nitrogen, sulfur and boron. The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The probe is cleaved by exonuclease (See column 20, lines 15-26).

Grossman et al do not disclose the kit and the probe attached to a capture ligand.

Babon et al. disclose a method for detecting one or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24).

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the probe of Grossman et al. with the Babon et al.'s capture ligand and agent attached to the oligonucleotide probe in order to construct eTag probe. Babon et al. teach directly capturing the probe to a solid support to easily wash away the unbound probe which increases the accuracy of the method instead of capturing the probe through the immobilized target sequence as disclosed by Grossman et al. It would have been prima facie obvious to add capture ligand to the probe of Grossman et al. in order to construct eTag probe to facilitate its binding.

In addition, constructing a kit including all components needed to carry out a method was routine practice in the art at the time of the instant invention. It would have been prima facie obvious to construct the kit comprising eTag probe and capture agent.

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In response to Applicant's argument filed 2/21/2003, Applicants argue that the capture ligand disclosed by Babon et al. is attached to a target sequence, not a probe. However, although the capture ligand disclosed by Babon et al. is attached to a target sequence, the target sequence works as a probe. Thus, the reference of Babon et al. applied is proper. Nevertheless, a probe attached with capture ligand for separation was well known in the art at time of the instant invention, for example, the reference of Murtagh et al. (5,744,306, issued 1998) discloses that a probe adapted with a moiety which can be captured to a solid support (See the Abstract and column 72, lines 64-67, claim 4).

The response further argues that the capture ligands of Applicants' are not used in a wash step as disclosed in Babon or in Murtagh, Jr et al., but rather are used to impart a mass and charge on uncleaved or partially cleaved probe that excludes them from the electropherogram of the cleaved eTag reporters. Any capture ligand used in separation was well known in the art at the time of the instant invention. Thus, the rejection is maintained.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705 (1995)) in view of Babon et al. (5,851,770 (1998)) as applied to claims 11-18 above, and further in view of Ullman et al. (6,251,581B1 (2001))

The teachings and suggestions of Grossman et al. and Babon et al. are discussed previously.

Grossman et al. and Babon et al. do not disclose the detectable labels which are the compounds listed in claim 24.

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Ullman et al. disclose a method for determining an analyte in a medium (See the Abstract). The method applies a chemiluminescent compound associated with an specific binding pair member (See column 4, lines 54-65 and column 5, lines 8-14). The compound has the same structure as the compound listed in claims 29 (See column 42-58).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply the chemiluminescent compound of Ullman et al. to the probe of Grossman et al in order to construct a set of electrophoretic tag probe. Ullman et al. disclose a chemiluminescent compound to bind to a specific binding pair complex so that the detection may be performed without heating the medium to produce light and conducted at a constant temperature (See column 7, lines 28-31). By avoiding heating, protein analytes would not be inactivated and thus the sensitivity of the method is increased. It would have been prima facie obvious to apply the fluorescent molecules to the electrophoric release tag to construct the set of electrophoretic tag probe to avoid inactivating protein analytes.

Summary

5. No claims are allowable.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

JT
June 20, 2003

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
6/30/03